

73049-474

1/29/2015

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Maria Herrero (Thomas Bade, Ph.D.)
Regulatory Manager
Valent BioSciences Corp.
870 Technology Way
Libertyville, IL 60048

JAN 29 2015

Subject: Label Amendment – change the use direction language for rice plant
Product Name: Massivo BioNik
EPA Registration Number: 73049-474
Application Date: 11/17/2014
Decision Number: 497832

Dear Ms. Herrero:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact Shenell Bolden by phone at (703) 347-0120, or via email at bolden.shenell@epa.gov.

Sincerely,



Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

CONCURRENCES							
SYMBOL	>	7511P					
SURNAME	>	Bolden					
DATE	>	01/15/15					

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VBC-40009
(Primary brand name)

Massivo BioNik™
Plant Growth Regulator
(Alternate brand name)

FOR USE AS A SEED TREATMENT

Active Ingredient	
S-Absciscic Acid.....	25.0% w/v
Other Ingredients.....	75.0% w/v
Total.....	100.0% w/v

Contains a total of 25 g of S-Absciscic Acid (S-ABA) in 100 ml of product. Application of BioNik™ (S-ABA) to parent seeds delays seedling emergence.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See next panel for First Aid Information.

EPA Registration No. 73049-474
EPA Establishment No. 33762-IA-001

Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048
1-847-968-4700

Net Contents: 1 quart (946 ml)

ACCEPTED

JAN 29 2015

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. **73049-474**

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FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also call toll-free 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-847-968-4700.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Do Not use treated seed for animal or human consumption. Do Not allow treated seed to contaminate grain or other seed intended for animal or human consumption.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Protective eyewear

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations
Users should: <ul style="list-style-type: none"> • Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. • Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. • Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

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ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-water or rinsate.

To prevent potential consumption by animals, cover or collect treated seeds spilled during loading.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Treated seed must not be used for or mixed with food or animal feed, or processed for oil. Seed commercially treated with a pesticide must be labeled as follows: "Treated Seed. Do not use for food, feed or oil."

The seed treater must add an EPA approved dye with the pesticide during the seed treatment process, unless dye is already on the seed [40 CFR 153.155(b)(1)].

GENERAL DIRECTIONS

Use only for treating seed. Use only as directed. Read the label thoroughly and make sure it is understood before making applications. BioNik™ delays seedling emergence of parent seed.

Application instructions:

- BioNik™ contains the active ingredient S-Absciscic Acid, commonly known as S-ABA. S-ABA is a potent Plant Growth Regulator found in plants.
- Undesired effects can result from any deviations from the label directions for applying BioNik™.
- Thoroughly mix BioNik™ by shaking or agitation before use.
- Apply BioNik™ to parent seed using commercial seed treatment equipment at a seed treatment facility. Not for use on agricultural establishments in hopper-box, planter-box, slurry-box or other seed treatment applications at or immediately before planting.

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COMPATIBILITY WITH OTHER AGRICULTURAL PRODUCTS

Compatibility and performance data for BioNik™ with other agricultural products is not available. Although BioNik™ is generally compatible with many other seed treatment formulations, if BioNik™ is to be mixed with other seed treatment products, first test on a small scale. Use caution in mixing with other products as incompatibility might occur. Incompatibility is indicated by an inhomogeneous seed treatment mixture, an uneven seed coating or poor adherence of the seed coating to the seed.

APPLICATIONS, RATES, AND TIMINGS

GERMINATION DELAY FOR HYBRID SEED PRODUCTION

The extent of delay resulting from BioNik™ is dependent on inbred or hybrid genetics. Conduct small scale evaluations of each inbred or hybrid to determine the dose required for the desired delay.

CROP	OBJECTIVE / BENEFIT	APPLICATION INSTRUCTIONS
Seeds for production of hybrid seeds	Delaying the seedling emergence and flowering timeline of parent seed; for delayed emergence and flowering of parent seed used in production of hybrid seed	Apply BioNik™ directly to desired parent seed for delayed germination or synchronization of flowering of parent seed used in production of hybrid seed. Make one application to seeds being treated (using commercial seed treatment equipment).

Delay of male corn parents for seed production

CROP	Delay of anthesis	Active Ingredient (milligrams a.i.) per kernel	BioNik™ (grams product) per 100 pounds seed (cwt); example using 1800 seeds/lb for inbred	BioNik™ (fluid ounces product) per 100 pounds seed (cwt); example using 1800 seeds/lb for inbred	Remarks
Corn	50 GDD	0.005 – 0.300 milligrams	3.6 – 216 grams	0.12 – 7.30 fluid ounces	Note on units: 0.1 milligram (mg) a.i./kernel = 100 micrograms (ug) a.i./kernel. Application rate depends on genetic background. BioNik™ rate per 100 pounds seed should be adjusted for seed number per lb for each inbred. Significant stand loss may occur and % loss depends on genetic background.
Corn	100 GDD	0.020 – 0.600 milligrams	14.4 – 432 grams	0.49 – 14.61 fluid ounces	
Corn	150 GDD	0.050 – 0.600 milligrams	36 – 432 grams	1.22 – 14.61 fluid ounces	

GDD = Growing Degree Days

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Delay of male sorghum parents

CROP	Delay of anthesis	Active Ingredient (milligrams a.i.) per kernel	BioNik™ (grams product) per 100 pounds seed (cwt); example using 18,000 seeds/lb (25 mg/seed) for inbred	BioNik™ (fluid ounces product) per 100 lbs seed (cwt); example using 18,000 seeds/lb (25 mg/seed) for inbred	Remarks
Sorghum	1 – 10 days	0.006 – 0.111 milligrams	40– 800 grams	1.35 – 27.05 fluid ounces	Note on units: 0.01 milligram (mg) a.i./kernel = 10 micrograms (ug) a.i./kernel. Application rate depends on delay desired and genetic background. BioNik™ rate per 100 pounds seed should be adjusted for seed number per lb for each inbred. Significant stand loss may occur at high rates for particular parent seed.

Delay of male pearl millet parents

CROP	Delay of anthesis	Active Ingredient (milligrams a.i.) per kernel	BioNik™ (grams product) per 100 pounds seed (cwt); example using 57,000 seeds/lb (8 mg/seed) for inbred	BioNik™ (fluid ounces product) per 100 lbs seed (cwt); example using 57,000 seeds/lb (8 mg/seed) for inbred	Remarks
Pearl Millet	1 – 10 days	0.002 – 0.070 milligrams	45 – 1600 grams	1.52 – 54.10 fluid ounces	Note on units: 0.01 milligram (mg) a.i./kernel = 10 micrograms (ug) a.i./kernel. Application rate depends on delay desired and genetic background. BioNik™ rate per 100 pounds seed should be adjusted for seed number per lb for each inbred. Significant stand loss may occur at high rates for particular parent seed.

Delay of rice parents

CROP	Delay of anthesis	Active Ingredient (milligrams a.i.) per kernel	BioNik™ (grams product) per 100 pounds seed (cwt); example using 18,000 seeds/lb (25 mg/seed) for inbred	BioNik™ (fluid ounces product) per 100 pounds seed (cwt); example using 18,000 seeds/lb (25 mg/seed) for inbred	Remarks
Rice	1 – 10 days	0.001 – 0.150 milligrams	7.2 - 1080 grams	0.24 – 36.52 fluid ounces	Note on units: 0.05 milligram (mg) a.i./kernel = 50 micrograms (ug) a.i./kernel. Application rate depends on delay desired and genetic background. BioNik™ rate per 100 pounds seed should be adjusted for seed number per lb for each inbred. Significant stand loss may occur at high rates for particular parent seed.

FACTORS AFFECTING RESPONSE TO BioNik™

S-ABA, the active ingredient in BioNik™, is a potent Plant Growth Regulator found in plants. S-ABA significantly delays emergence when applied to seeds.

In addition to proper application technique, environmental and cultural factors will affect a seed or seedling's response to treatment with BioNik™. Do not use this product on old, weak, or damaged seed. Excessive stand loss could result from such use.

Different varieties or cultivars within a given plant species may require a higher or lower rate of BioNik™ to achieve the desired effects.

Determining Optimal Rates: Optimal BioNik™ rates will vary according to the desired emergence and flowering delay. Different varieties or cultivars of the same species may respond differently to BioNik™. Therefore, to determine response levels treat or test a small number of seeds before applying BioNik™ to a large number of seeds.

DO NOT exceed the maximum stated rate.

Environmental Factors:

Heavy irrigation/rain immediately after planting may reduce efficacy.

Planting in a dry seedbed may extend germination delay. Therefore, plant in moist seed bed.

Low or high soil temperatures may impact the period of germination delay.

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STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage

Keep container tightly closed when not in use. Store product in a cool place. Avoid extended storage conditions at temperatures above 25°C (77°F). Avoid exposure of product to light or sunlight.

Pesticide Disposal

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Container Handling

Nonrefillable container. Do not reuse or refill this container.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after flow begins to drip. Fill container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

Warranty and Disclaimer Statement:

To the extent consistent with applicable law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.